FDA Patient Safety News: Show #65, July 2007

FDA Clears First Respirator for General Use

FDA has cleared for marketing the first respirators to be used by the public during public health emergencies, such as an influenza pandemic. Called the 3M Respirator 8612F and 8670F, these products will be available without a prescription.

These devices are N95 filtering respirators, and they were originally designed for occupational use. They are intended to filter out at least 95 percent of small airborne particulates.

An N95 respirator can be used in different circumstances than a surgical mask, isolation mask, or dental mask. These masks protect against large airborne particulates, microorganisms and body fluids so they would be used if a person were caring for an open wound, exposed to spattered blood or vomit from someone else, or sick himself.

The N95 respirator protects against small droplets and particulates in the air that are likely to get through a surgical mask. So they would be used if someone were exposed to small droplets caused by coughing, or caring for someone with TB.

When used in occupational settings, each individual respirator is selected to fit the worker who will use it. This kind of fit testing is not generally employed outside the workplace now and would probably not be feasible during a public health medical emergency.

The manufacturer, the 3M Company, did evaluate the fit in a group of healthy volunteers, and although the results did vary from person to person, everyone achieved some reduction in exposure to airborne particulates. These respirators are sized for adults and may not form a proper fit on children. In addition, anything that comes between the respirator and the face, such as facial hair, may interfere with its fit.

There are other people who may have trouble using these devices. For example, those with pre-existing heart or lung disease may have difficulty breathing through a respirator. Finally, these respirators are for one-time use, so after they are used, they should be discarded.

Additional Information:

FDA Press Release. FDA Clears First Respirators for Use in Public Health Medical Emergencies. May 8, 2007. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108911.htm

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First Skin Patch to Treat Parkinson's Disease

FDA recently approved the first transdermal patch intended to treat the symptoms of early Parkinson's disease. The patch is called Neupro, and it is made by Schwarz Biosciences.

The Neupro patch delivers the drug rotigotine continuously through the skin. Rotigotine is a dopamine agonist, so like other drugs of this type, it works by activating dopamine receptors in the body. The patient applies a new patch every 24 hours.

The effectiveness of Neupro was demonstrated in three studies that involved over 1,100 patients with early Parkinson's disease who were not taking other Parkinson's medications. Patients in these studies experienced

improvement in activities of daily living and motor skills.

The most common side effects included reactions at the application site, dizziness, headache, nausea, vomiting, somnolence, and insomnia. Some patients also reported falling asleep during daily activities such as driving, sometimes without warning.

Additional Information:

FDA Press Release. FDA Approves Neupro Patch for Treatment of Early Parkinson's Disease. May 9, 2007. http://www.fda.gov/bbs/topics/NEWS/2007/NEW01631.html

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New Warnings on Suicidality in Young Adults Taking Antidepressants

FDA has proposed that the makers of all antidepressant drugs warn in the product labeling that patients 18 to 24 years old who are on these drugs may be at increased risk for suicidal thinking and suicide attempts. The new warning would be added to the black box section of the label, which already warns about this risk in children and adolescents.

The proposed labeling change would also state that the increased risk has not been observed in patients older than 24, and that patients over 65 taking antidepressants actually have a decreased risk of suicidality. The warning also emphasizes that psychiatric disorders themselves are the most important causes of suicide.

Affected Products:
- Anafranil (clomipramine)
- Asendin (amoxapine)
- Aventyl (nortriptyline)
- Celexa (citalopram hydrobromide)
- Cymbalta (duloxetine)
- Desyrel (trazodone HCl)
- Elavil (amitriptyline)
- Effexor (venlafaxine HCl)
- Emsam (selegiline)
- Etrafon (perphenazine/amitriptyline)
- Fluvoxamine maleate
- Lexapro (escitalopram oxalate)
- Limbitrol (chlordiazepoxide/amitriptyline)
- Ludiomil (maprotiline)
- Marplan (isocarboxazid)
- Nardil (phenelzine sulfate)
- Nefazodone HCl
- Norpramin (desipramine HCl)
- Pamelor (nortriptyline)
- Parnate (tranylcypromine sulfate)
- Paxil (paroxetine HCl)
- Pexeva (paroxetine mesylate)
- Prozac (fluoxetine HCl)
- Remeron (mirtazapine)
- Sarafem (fluoxetine HCl)
- Seroquel (quetiapine)
- Sinequan (doxepin)

- Surmontil (trimipramine)
- Symbyax (olanzapine/fluoxetine)
- Tofranil (imipramine)
- Tofranil-PM (imipramine pamoate)
- Triavil (perphenazine/amitriptyline)
- Vivactil (protriptyline)
- Wellbutrin (bupropion HCl)
- Zoloft (sertraline HCl)
- Zyban (bupropion HCl)

Additional Information:

FDA MedWatch Safety Alert. Antidepressant Medication Products. May 2, 2007.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm153362.htm

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False Negative Results with VITROS Troponin I Reagent Pack

Ortho-Clinical Diagnostics has notified healthcare professionals about a recall of the company's VITROS Troponin I Reagent Pack because of the potential for false negative results when troponin levels are only slightly elevated. A false negative might indicate that a patient had not experienced a heart attack when in fact an MI had actually taken place.

The affected lot numbers are 3151 and 3170. Clinical labs who have these lots have been instructed to stop using the product, and notify physicians who have ordered the test in recent weeks. Labs with questions on this recall can contact the company at 1-800-421-3311.

Additional Information:

FDA MedWatch Safety Alert. Ortho-Clinical Diagnostics VITROS Immunodiagnostic Products Troponin I Reagent Pack. May 7, 2007.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm152661.htm

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Recall of Certain Sleep Apnea Air Flow Generators

The device company ResMed is recalling about 300,000 of the company's S8 flow generators. These devices treat patients with obstructive sleep apnea by providing continuous positive air pressure (CPAP).

The problem is that some of these devices have developed a short circuit in the power supply connector, causing the device to fail. In a few cases, the device overheated. If that happens, there is a possibility that material around the device could catch fire. The company says that there has been no significant property damage or patient injuries to date.

The recall affects all Model S8 devices manufactured between July 2004 and May 15, 2006. To identify these devices, check both the part number and the serial number, which are located on the name plate on the bottom of the device.

ResMed is providing patients with replacement devices. The company says that patients can continue to use their S8 flow generators until they get a replacement, except for those patients who require supplemental oxygen. These patients should not use oxygen with an affected device. Instead, they should immediately

contact their home healthcare provider for a replacement.

As with any electrical device, patients should also make sure that their flow generators are placed on a hard clean surface, and that the area around the device is clear during use. They should stop using the device if there are any signs of electrical failure, such as intermittent power, crackling sounds, sparking or a charred smell. For more information contact the ResMed S8 Replacement Call Center at 888-899-8991.

Additional Information:

FDA MedWatch Safety Alert. ResMed S8 Flow Generators (Continuous Positive Air Pressure or CPAP): S8 Compact, S8 Escape, S8 Elite, and S8 AutoSet Vantage. April 24, 2007.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm152664.htm

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Warning about Tracheoesophageal Fistula with Avastin

Genentech recently alerted healthcare professionals about patients with limited-stage small cell lung cancer who developed tracheoesophageal (TE) fistulae after receiving a treatment regimen that included Avastin. Avastin (bevacizumab) is approved to treat certain patients with non-small cell lung cancer and colorectal cancer, but it is not approved for small cell lung cancer.

The patients were enrolled in a clinical study of combined chemotherapy and radiation plus Avastin. Two confirmed cases of TE fistula, one of them fatal, were reported in the first 29 patients enrolled in this study. Another fatal event was also reported, where TE fistula was suspected but not confirmed. All three events occurred during the Avastin maintenance phase of the study in patients who had been experiencing persistent esophagitis. Patient enrollment in the study has been stopped.

The current labeling describes GI fistulae in patients with colorectal and other types of cancer who were given Avastin. Genentech says the company will update the product label to provide more detailed information on the incidence of all cases of fistula in patients treated with Avastin.

Additional Information:

FDA MedWatch Safety Alert. Avastin (bevacizumab). April 21, 2007.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm150835.htm

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New Guidelines on MRI Safety

Serious and sometimes fatal patient injuries associated with magnetic resonance procedures are an ongoing safety concern.. These issues can include burns from electrodes and cables during MRI exams, injuries in patients who have implanted neurological stimulators, burns in patients wearing transdermal patches, and about metallic objects brought into the MR unit that have flown across the room and killed people.

MR-associated accidents, many life-threatening or fatal, are still occurring, and this has caused continued concern in the radiology community. In order to help reduce the risk, the American College of Radiology (ACR) has issued a comprehensive update to its 2004 white paper on MR safety, called the ACR Guidance Document for Safe MR Practices. This document covers every aspect of MR safety, from the design of the MR suite and the qualifications of personnel to screening patients and what to do in an emergency.

Personnel who work in or near a magnetic resonance facility should have and read this document. But it also

contains information that may be useful for non-radiology personnel who prepare patients for MR procedures -- for example, on managing the potential risks of aneurysm clips, pacemakers, dermal drug delivery patches and gadolinium-based contrast agents.

Additional Information:

Kanal, E.; Barkovich, A.J.; Bell, C; et al. ACR Guidance Document for Safe MR Practices. 2007. American Journal of Roentgenology. Volume 188, Issue 6. June 2007.
http://www.acr.org/SecondaryMainMenuCategories/quality_safety/MRSafety/safe_mr07.aspx

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Avoiding Dangerous Mix-ups between Insulin and Heparin

The New Jersey Department of Health and the Institute for Safe Medication Practices (ISMP) have each recently warned about several different ways that dangerous mix-ups can occur between insulin and heparin.

Some of these mix-ups happened when patients receiving total parenteral nutrition had insulin added to their TPN bags instead of heparin. In one case, a premature infant in the NICU had a blood glucose level of 17 mg/mL several hours after being started on a TPN infusion. Despite multiple administrations of dextrose, the hypoglycemia did not completely resolve until TPN was stopped. A later analysis showed that the fluid contained insulin, not heparin. This infant's long term outcome has not yet been determined, and ISMP describes two similar incidents where the babies died.

These kinds of errors can happen other ways. For example, two patients who were not diabetic died after being injected with insulin instead of heparin during a vascular catheter flush procedure. In a different case, a nurse erroneously transcribed a verbal order to resume an insulin drip as "resume heparin drip." And in yet another case, a pharmacist entered an order for heparin 500 units into the computer as "regular insulin 500 units."

ISMP says several factors contribute to these mix-ups. First, the 10 mL vials of insulin and heparin often look similar. Both insulin and heparin are typically used every day during each shift, so these similar-looking vials are often next to each other on a counter, a drug cart, or under a pharmacy IV admixture hood. Both drugs are dosed in units. And ISMP says that as insulin infusions become more common, the risk of a mix-up may be growing.

The New Jersey Department of Health and ISMP recommend a number of strategies to reduce the risk of these kinds of mix-ups. Here are some of them:

• Do not keep insulin and heparin vials next to each other.

• To avoid using vials that look alike, consider using heparin bags of 100 units/mL. Heparin prefilled syringes could be used for admixtures. And consider providing insulin to patient care units in pen devices rather than vials.

• Require independent double-checks of IV insulin and IV heparin doses and infusions, and also an independent double-check through each step of preparing TPN solutions.

• Write verbal orders directly on order forms and then verify the accuracy by reading back the order.

• Finally, when a patient develops unexpected, unexplained hypoglycemia, consider the possibility that a medication error may have occurred and take the following steps: discontinue all current infusions and hang

new solutions, treat the patient as necessary with dextrose, and check for unintended additives by sending the infusion bag(s) for analysis.

Additional Information:

ISMP Medication Safety Alert! Action needed to prevent dangerous heparin-insulin confusion. May 3, 2007.
http://www.ismp.org/Newsletters/acutecare/articles/20070503.asp

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New Food Safety Education Kit for Moms-to-Be

FDA is now offering a free educational kit that nurses, midwives and other educators can use to make presentations on food safety for pregnant women. The kit contains an Educator's Resource Guide with background and facts on food safety, reproducible handouts and a 20-minute video. The materials can be found on a special FDA web site, along with a printable poster that can be displayed in your institution and a set of PowerPoint slides for your presentation. All of these materials are available in both English and Spanish.

Pregnant patients can be referred to the web site for more food safety tips. Among the topics covered are food borne risks, including Listeria, methylmercury and toxoplasma, as well as the four key steps needed to prevent food borne illnesses. The kit can also be obtained by calling FDA at 1-888-SAFEFOOD.

Additional Information:

FDA/CFSAN Video. Food Safety for Moms-To-Be.
http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm089619.htm

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